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**Filed** : August 15, 2001

### **REMARKS**

Applicant thanks the Examiner for the courteous interview conducted on October 5, 2004, and the helpful comments provided therein.

Presently, original claims 7, 10, and 31, previously presented claims 1, 3-6, 8, 27-28, 35, 37, 39, 41, 43, 45, 47, and 49-75, and currently amended claims 11, 36, 38, 40, 42, 44, and 46 are before the Examiner. In the current amendment, Claims 2, 33-34, and 48 have been canceled without prejudice to, or disclaimer of, the subject matter contained therein. Applicant maintains that the cancellation of a claim makes no admission as to its patentability and reserves the right to pursue the subject matter of the cancelled claim in this or any other patent application.

Applicant addresses the Examiner's specific rejections below.

#### **Election/Restriction**

Applicant respectfully acknowledges the Examiner's amendment rejoining independent Claim 8, and dependent claims 45, 54, 62, and 70 to elected Group I.

#### **Specification**

The Examiner has objected to the use of hyperlinks in the specification. Accordingly, the Applicant has amended the specification to remove the hyperlinks.

The Examiner has objected to the recitation of the word "adjuvant other than ribavirin" but has indicated that the priority document U.S. Provisional Patent Application No. 60/229,275, which is incorporated by reference in its entirety, contains supporting disclosure for other adjuvants. (See, U.S. Provisional Application No. 60/229,275, p.3, ll. 25-28). The supporting disclosure for adjuvants other than ribavirin has been added by amendment. Thus, no new matter has been introduced by this amendment.

#### **Priority**

The Examiner has objected to Applicant's claim to priority to Application No. 09/705,547. Applicant has amended the specification to remove the priority claim to Application No. 09/705,547.

Applicant acknowledges the Examiner's objection to Applicant's claim for domestic priority to U.S. Provisional Application No. 60/225,767, filed August 17, 2000 with reference to

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Claim 75. Support for Claim 75 can be found in U.S. Provisional Application No. 60/229,175, filed August 29, 2000, to which Applicant claims priority.

**Rejection under 35 U.S.C. § 101, subject matter**

Claims 34, 36, 38, 40, 42, 44, 46 and 72 are rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Examiner objected to the recited language “A cell comprising the nucleic acid. . .”, as reading on naturally occurring materials. Specifically, the Examiner argued the open claim language could read on the whole HCV genome. According to the Examiner, the claims would read on an infected patient harboring HCV-infected cells.

To expedite allowance of the instant application, Applicant has canceled Claim 34 and has amended Claims 11, 36, 38, 40, 42, 44, 46, and 72 to include the language “isolated”, as suggested by the Examiner. Accordingly, Applicant respectfully requests the Examiner withdraw the rejection under 35 U.S.C. § 101, as claiming non-statutory subject matter.

**Rejection under 35 U.S.C. § 112, first paragraph – enablement**

Claims 55-70 and 74-75 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Examiner states that the specification is enabling for a composition comprising a vector with SED ID NO: 1 or a fragment thereof in combination with ribavirin and/or an adjuvant for inducing an enhanced immune response, but it does not provide enablement for an immunogenic composition comprising an isolated nucleic acid sequence comprising SEQ ID NO: 1 or a fragment thereof in combination with ribavirin or an adjuvant. According to the Examiner, the state of the art does not teach that DNA lacking expression machinery, e.g., provided by a vector, can be immunogenic. The Examiner also states that the specification does not teach SEQ ID NO: 1 (or the claimed variants thereof) plus ribavirin outside of the context of vector DNA as a composition. The Examiner further notes that the open language of the claims reads on the whole HCV genome, which is capable of producing infectious HCV in vitro and in vivo, as reported by Lohman et al.

Claims 55-70 and 74-75 refer back to Claim 47. Claim 47 recites: “A composition comprising the nucleic acid of Claim 1.” A vector is a composition. As Claim 47 contains the open term “comprising”, Applicant respectfully submits that the claims encompass SEQ ID NO: 1 (and variants thereof) within a vector DNA capable of expressing the polypeptides encoded

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therein. Accordingly, Applicant respectfully submits that Claims 5-70 and 74-75 are enabled.

Regarding the Examiner's concern that the claims read on the whole HCV genome, Applicant respectfully submits that one of skill in the art would understand that the claimed invention is not directed to the whole HCV genome. Specifically, because the state of the art, including Lohman et al., teaches that the complete HCV genome produces infectious HCV, one of skill in the art would appreciate that this would be an inoperable embodiment of the claimed invention. Claims that encompass inoperable embodiments are patentable, and the standard for enablement is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative (MPEP § 2164.08(b)). The open language "comprising" in Claims 55-70 and 74-75 was discussed with the Examiner in the October 5, 2004 telephonic interview, at which time the Examiner agreed that the language "comprising" was acceptable given the argument above. Therefore, because the open language "comprising" in the claims encompasses embodiments wherein SEQ ID NO: 1 (or claimed variants thereof) is in a vector capable of expressing the polypeptides encoded by the claimed sequences, and the Examiner agreed that "comprising" was acceptable because one of skill in the art would readily be able to ascertain that the use of the complete HCV genome is inoperable, Applicant respectfully requests that the rejections of Claims 55-70, and 74-75 under 35 U.S.C. § 112, first paragraph, be withdrawn.

### **Double Patenting**

Claims 27-28 and 47-74 are provisionally rejected under the doctrine of double patenting as being unpatentable over Claims 21 and 28 of co-pending Application No. 09/929,955 ('955 Application). The Examiner states Claims 21 and 28 of the '955 Application are directed to an immunogenic composition comprising the nucleic acid sequence of SEQ ID NO: 16 and ribavirin. The Examiner states SEQ ID NO: 16 of the '955 Application is identical to SEQ ID NO: 1 of the instant application. Claims 8, 45, 46, and 54 are provisionally rejected under the doctrine of double patenting as being unpatentable over Claims 1-7 and 38-41 of co-pending Application No. 10/037,047 ('047 Application). The Examiner states Claims 1-7 and 38-41 of the '047 Application are directed to an isolated nucleic acid, a cell, a vector, and a composition comprising at least 50 consecutive nucleic acids of SEQ ID NO: 35, which has 100% homology to the nucleic acid claimed in the rejected claims.

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A terminal disclaimer referencing the '955 and the '047 Applications accompanies this Amendment and Response. Therefore, Applicant respectfully requests that the Examiner withdraw the rejection for double patenting.

**Rejection under 35 U.S.C. § 102(b), (e)**

Claims 2, 33, 34 and 48 are rejected under 35 U.S.C. § 102(b) as being anticipated by Brechot *et al.* and Houghton *et al.* Claims 2, 33, 34, and 48 are also rejected under 35 U.S.C. § 102(e) as being anticipated by Yanagi *et al.* and Chien *et al.*

To expedite allowance of the instant application, the Applicant has canceled Claims 2, 33, 34 and 48, thereby obviating the rejection. Applicant believes to have overcome the rejections under 35 U.S.C. § 102 and requests that the Examiner withdraw the rejections.

**CONCLUSION**


In view of the above amendments and comments, Applicant believes that the instant application is in condition for allowance. However, if the Examiner has any questions, the Examiner is respectfully requested to call Applicant's attorney, Eric S. Furman at (619) 687-8643.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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